

Remarks

The various parts of the Office Action (and other matters, if any) are discussed below under appropriate headings.

General Comments

Independent claims 1, 13 and 15 have been amended to remove the term "withdrawal", as the use of this term was superfluous.

Claim Rejections - 35 USC § 102 and § 103

Claims 1-8, 11, 13-16, and 20 stand rejected as being anticipated and/or obvious over *Anderson* (U.S. 2002/0168618), while claims 22-23 stand rejected as being anticipated by *Kucharczyk* (U.S. 6,026,316). Claims 7, 9, 10, 17-19 and 24-25 stand rejected as being unpatentable over *Anderson* in view of *Lemelson* (U.S. 5,919,135) and/or *Raghaven* (U.S. 6,549,803).

Claims 2, 14 and 22-23 have been canceled herein and thus the rejection of these claims is moot. Withdrawal of the rejection of the remaining claims is respectfully requested for at least the following reasons.

Independent claim 1 stands rejected as being anticipated by *Anderson*. Independent claim 1 has been amended to additionally recite *determining from the simulation data if a desired infusion plan for administration of a substance into a patient can be obtained*. For example, once an infusion "pre-plan" has been developed, a simulation of that pre-plan can be performed. This simulation can be used to evaluate the effectiveness of the pre-plan and, based on the simulation results, adjustments to the pre-plan can be made.¹

As previously discussed, the system of *Anderson* is a training device that enables a trainee surgeon, for example, to become acquainted with a particular procedure and/or a particular piece of equipment. For example, the training device of *Anderson* provides force feedback or resistance as a syringe is inserted in a manikin, thereby simulating the force required to insert a syringe in a live patient. Further, the training device can simulate other procedures, including a simulation of a contrast medium injected into the manikin. The simulated injection may be loosely based on certain parameters, such as an injection volume and rate that are selectable from a user interface. Once the parameters are set, the simulated injection is initiated, wherein the injection is shown on a display so as to give the appearance that an injection is occurring.

¹ See page 6, lines 4-14 of the application.

The training device of *Anderson*, however, does not provide simulation data that can be used in-silico, namely on a computer system without any haptic feedback, to determine if a desired infusion plan can be obtained. *Anderson* simply provides haptic and visual feedback to make it appear an infusion is occurring (regardless of its precise location in the actual body of a patient). The visual feedback itself, however, does not provide any quantitative data with respect to whether or not a desired infusion plan can be obtained and is medically feasible or sensible.

Claim 1 also recites that if the desired infusion plan can be obtained, a navigation system is used to position the infusion catheter in the body of a patient as specified by the plan.

As discussed above, *Anderson* is concerned with training a physician various infusion techniques via a manikin, (which by definition cannot reflect particular properties of a patient), and not with treating an actual patient. No mention has been found in *Anderson* that once it is determined that a desired infusion plan can be obtained, a navigation system is used to position the infusion catheter in the body of the patient as specified by the infusion plan.

The remaining art to *Kucharczyk*, *Lemelson* and *Raghaven* has not been found to make up for the deficiencies of *Anderson*. Similar comments apply with respect to independent claims 13 and 15.

Accordingly, withdrawal of the rejection of claims 1, 13 and 15 is respectfully requested.

The remaining claims depend from either claim 1, 13 or 15 and, therefore, can be distinguished from the cited art for at least the same reasons.

Further, claim 8 recites that catheter parameters are used for planning the infusion. The Examiner contends that *Anderson* teaches this feature at paragraph [0157]. Paragraph [0157] states that a physical model can be used to simulate a device. There is no mention in paragraph [0157], however, that catheter parameters are used to plan the infusion.

Claim 9 recites that the distribution of the substance is simulated based on, *inter alia*, catheter parameters. Claim 10 recites wherein a target volume and/or distribution of the substance in the patient is pre-set, and catheter parameters and parameters of the substance are based on the preset target volume and preset distribution.

The Examiner contends that *Anderson* discloses “that the distribution of the substance is simulated based on patient parameters obtained from captured patient data and catheter parameters”. The Examiner also contends that *Anderson* discloses “that a target volume and/or distribution of the substance in the patient is preset, and that catheter parameters are

based on this preset target volume and distribution". The Examiner, however, fails to cite to the portion or portions of *Anderson* that allegedly teach these features. The undersigned has reviewed *Anderson* and can find no such teachings. More specifically, a word search for the term "catheter" has not revealed any discussion of "catheter parameters", wherein such catheter parameters are used to simulate the distribution of the substance. Further, no discussion was found in *Anderson* with respect to basing catheter parameters on a target volume and/or distribution of the substance. *Lemelson* has not been found to make up for the above deficiencies of *Anderson*.

Accordingly, withdrawal of the rejection of claims 3-11, 16-20 and 24-25 also is respectfully requested.

Conclusion

In view of the foregoing, request is made for timely issuance of a notice of allowance.

Respectfully submitted,

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